REMARKS

I. SUMMARY OF THE OFFICE ACTION

The office action summary page indicates that claims 1-5 and 12-42 are pending and rejected, and that the office action is non final. The office action objects to the numbering of the claims (because two claims were both numbered 22); notes that the rejections based upon Cook in view of Drent and LeClercq were withdrawn; rejects claim 3, 12, 20, 21, 34, 35, and 42 under the second paragraph of 35 USC 112; rejects claims 1-5 and 12-42 under 35 USC 103 based upon Cook (USP 5,919,451) and LeClercq (Metabolism of very low density ....); and provisionally rejects claim s 1, 2, 16, 18, 19, 26-28, 32, and 33 for non-statutory double patenting over claims 1, 8, 14, 18, 31, 47, and 51 of 08/888,202.

II. SUMMARY OF CLAIMS

Claims 20 and 21 are canceled by this amendment. Claims 1-5 and 12-19, and 22-42 are pending.

Claims 1, 16, 25, 26, 29, 32, 36, 39, and 42 are the independent claims.

Independent claims 1, 16, and 25 are substantial analogs of one another. Independent claims 26, 29, and 32 are substantial analogs of one another directed to the novel method of making, composition so made, and method of using - - the disclosed liposome-encapsulated anti-lipase antibody.

Claims 36-42 describe the composition, method of making, and method of using the novel composition, by defining the process disclosed in the specification at page 4 lines 9-17 (example 2) used to prepare the liposome - anti-lipase antibody composition. The disclosed liposome - anti-lipase antibody composition is believed to be novel.

III. RESPONSE TO CLAIM OBJECTIONS

Item 2 in the office action indicates that the claims are not consecutively numbered and also requires the applicant to "note such correction in Applicant's response to this Office Action."

In response, the applicant notes that the claim numbering was incorrect. The applicant amends the claims to show the correct claim numbering.

IV. **SUMMARY OF REJECTIONS WITHDRAWN**

In item 5 in the office action, the examiner notes that she has withdrawn the prior rejections of claims 1-5 and 12-42 based upon Cook, Drent, and LeClercq, in light of the applicant's arguments.

In item 4, in the office action, the examiner states that "rejections not reiterated herein have been withdrawn." Those rejections included rejections under 35 USC 112 of claim 1 (preamble not indefinite); 17 (as amended to correct for lack of antecedent basis); 23 (amended to not be a duplicate of another claim); 36-40 (as amended by replacing "a new solution" with "a solution containing said liposomes"); and 41 (as amended to independent form with no change in scope).

V. **REJECTION OF CLAIMS AS INDEFINITE UNDER 35 USC 112, SECOND PARAGRAPH**

The current office action rejected claims 3, 12, 20, 21, 34, 35, and 42 under the second paragraph 35 USC 112, as indefinite for failing to particularly point out and distinctly claim subject matter.

A. **Claim 3**

Claim 3 depends from claim 1, which depends from claim 1. Claims 1-3 read as follows.

1. (Previously Presented) A method comprising: feeding an animal food and a liposome-encapsulated anti-lipase antibody.

2. (Previously Presented) The method of claim 1 wherein said anti-lipase antibody is an avian antibody.

3. (Previously Presented) The method of claim 2 further comprising at least one of storing said liposome-encapsulated anti-lipase antibody in a wet state and freeze drying said liposome-encapsulated anti-lipase antibody.

The prior office action rejected also rejected claim 3 under the second paragraph 35 USC 112, stating that:

> Claim 3 is confusing in relation to claim 1 from which it depends because claim 1 appears to recite a "method of using [a composition]" claim such as for feeding an animal, whereas the instant claim recites "storing" the composition in a particular state, i.e. wet state or freeze dried, which appears to be encompassed in a "method of forming"

claim. Accordingly, it is unclear what structural and functional cooperative relationship exists between the elements of the instant claim and those of claim 1 from which it depends. [Office action page 3 lines 13-19.]

The applicant traversed the prior rejection of claim 3 because the examiner's conclusion that claim 1 was limited to a method of feeding was incorrect. Claim 1 recites in pertinent part "A method comprising: ".... The open recitation "comprising" indicates that any other additional steps are within the scope of claim 1. Therefore, the additional step defined by claim 3 of "storing" is a proper additional limitation to the subject matter defined by claim 1.

The examiner's statements in the prior office action regarding claim 3 also implied that method of using and method of making steps in one claim were improper. In response, the applicant noted that 35 USC 101 contains no such limitation on method claims, and it defines what is suitable subject matter for method claims. It states as follows:

35 U.S.C. 101 Inventions patentable.

Whoever invents or discovers any new and useful ***process***, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Thus, the applicant concluded that there was no statutory basis to reject a claim reciting both method of making and method of using steps.

As to the examiners concerns about a "structural and functional cooperative relationship", the applicant noted that such a relationship need not be defined by a claim, and noted that, in the context of the disclosure, storage followed by feeding was disclosed, and disclosed as useful steps.

Now turn to the current office action's rejection of claim 3. In the current office action, the examiner states that:

Claim 3 is indefinite in reciting method steps of making a composition which depends from a method of using a composition. Accordingly, it is unclear how the method steps in claim 3 should cooperatively, structurally, and functionally apply to claim 1 from which it depends. [Office action page 4 lines 6-9.]

The examiner specifies no argument relating to the actual limitations defined by the method steps. Thus, it appears that the examiner has concluded that a claim reciting both method of making and

a method of using steps is per se indefinite. That is a purely legal conclusion, and it is incorrect. BPAI case law, which is binding upon the examiner, contradicts the examiner's legal conclusion. See Ex parte Hanna, Appeal No. 2005-2464, application 10/095,715 (November 22, 2005, BPAI) Caroff, Hanlon, and Poteate, APJs. A copy of Ex parte Hanna is attachment 13 to this response.[1] In Hanna, the panel reversed rejections under 35 USC 112, second paragraph under identical circumstances to those present here. In Hanna, claims containing both method of making and method of using steps were held to be not indefinite under 35 USC 112, second paragraph, and also not improper under 35 USC 101. In Hanna, the panel stated:

> All of the appealed claims depend from independent claim 16 which is directed to a "method for the formation of a particulate product." Claim 220, reproduced below, is representative of the dependent claims on appeal:
>
> 220. Method according to claim 16 further comprising placing said particulate product in an inhaler. ***
>
> Based upon the record before us, we are compelled to reverse each of the rejections at issue essentially for the reasons set forth in the appellants' brief and reply brief.
>
> Specifically, with regard to the rejection under 35 U.S.C. 112, we agree with the appellants that the subject dependent claims do, in fact, further limit the independent claim from which they all depend.
>
> According to the examiner, the recited steps in the appealed claims which relate to a *use* of a particulate product cannot be considered part of a method which has, as its recited purpose, the "*formation* of a particulate product." We disagree. "Formation" is merely an expression of one expected or intended outcome of the claimed process and does not, in any way, preclude additional limiting steps in the process which may provide additional results or benefits. For example, in this case it is clear that the method of claim 220 includes the additional step of placing the particulate product in an inhaler for the purpose of dispensing the product. [Ex parte Hanna, Appeal No. 2005-

[1]A copy of Ex parte Hanna, Appeal No. 2005-2464, application 10/095,715 (November 22, 2005, BPAI) Caroff, Hanlon, and Poteate, APJs is attachment 13.

2464, application 10/095,715 (November 22, 2005, BPAI), at pages 1-3; emphasis added.]

What the appellant stated in their reply brief in Hanna, which reasoning was incorporated by reference in the decision in Hanna, was the following:[2]

I. **The Rejections of Claims 220, 221 and 254-258 Under 35 USC 112, Second Paragraph**

In the Examiner's Answer mailed November 16, 2004, the examiner asserts at page 4 lines 8-14 that:

It is Appellant's assertion that because claims 220, 221 and 254-258 contain additional steps they further limit the subject matter of claim 16. The claims in question do contain additional steps but they do not further limit the subject matter of claim 16. Claim 16 is directed to a process of making particles. *Filling an inhaler or inhaling (the subject matter of claims 220, 221 and 254-258) is not a step in the formation of particles. Since this subject matter is not a step in the formation of particles it cannot further limit the subject matter of claim 16.* [Examiner's Answer at page 4 lines 8-14.]

In reply, the applicants respectfully point out that *the examiner provides no reasoning supporting these assertions.* The appeal brief explains why these rejections are improper.

II. **The Rejections of Claims 220, 221 and 254-258 Under 35 USC 101**

In the Examiner's Answer mailed November 16, 2004, the examiner asserts at page 4 line 18 to page 5 line 6 that:

It was not the Examiner's intent to suggest that these claims are product by process claims. The claims are clearly not. They are method claims. The product by process section of the MPEP was cited to show that product by process claims are the exception to the rule that claims may contain only one class of invention. Since the present claims are not product by process claims they do not fall within the exception to

---

[2]A copy of the reply brief referred to in Ex parte Hanna, is attachment 14.

only one class of invention in a claim.

> *Appellants argue that the claims do not define more than one class of invention because all of the claims are method claims. Claim 16 is a method of making. Claims 220, 221 and 254-258 are methods of use. A method of making and a method of use are different categories of invention.* [Examiner's Answer at page 4 line 18 to page 5 line 6.]
>
> *In reply, the applicants respectfully point out that 35 USC 101 makes no distinction between a method of making and a method of using.* [Reply brief in 10/095,715, pages 1-3; italics added for emphasis.]

Thus, the examiner's factual basis for rejecting claim 3 as indefinite, which is that it recites steps both making and using steps, is both improper and contrary to the holding in Hanna.

The examiner's reasoning supporting why she rejected claim 3 is that "it is unclear how the method steps in claim 3 should cooperatively, structurally, and functionally apply to claim 1 from which it depends." Given the fact that the examiner did not refer to any particular step limitations in her analysis, the examiner's reasoning appears to be limited to a conclusion that making and using steps in the same claim are per se indefinite, despite her reference to "cooperatively, structurally, and functionally". However, the applicant also addresses the examiner's "cooperatively, structurally, and functionally" statement assuming the possibility that the examiner intended to relate that language to actual limitations of the claimed steps. That reasoning does not support rejection under 35 USC 112, second paragraph, for the following additional reasons.

35 USC 112, second paragraph reads:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

First, 35 USC 112, second paragraph requires definiteness, not a "cooperatively, structurally, and functionally" relationship. Therefore, the examiner is applying a legal criteria not present in the statute. Therefore, rejection based upon lack of compliance with that criteria is improper.

Second, the conclusion that the method of making and method of using steps are not "cooperatively, structurally, and functionally" related is not logical. A method of making is necessarily a prerequisite to a method of using, and therefore, "cooperatively, structurally, and functionally" relates

to the method of using. Hanna, supra.

For all the foregoing reasons, the rejection of claim 3 under 35 USC 112, second paragraph is improper and should be withdrawn.

B. **Claim 12**

In the office action, the examiner rejects claim 12, stating that:

> Claim 12 is indefinite in reciting method steps of making a composition which depends from a method of using a composition. Accordingly, it is unclear how the method steps in claim 12 should cooperatively, structurally, and functionally apply to claim 1 from which it depends. [Office action mailed 2/7/2007 page 4 liens 10-13.]

Claim 12, and claim 1 from which claim 12 depends, read as follows.

> 1. (Previously Presented) A method comprising: feeding an animal food and a liposome-encapsulated anti-lipase antibody.
>
> 12. (Previously Presented) The method of claim 1 further comprising forming said liposome-encapsulated anti-lipase antibody prior to said feeding.

Claim 12 therefore defines a method of forming and using an animal food including a liposome-encapsulated anti-lipase antibody. For substantially the same reasons discussed at length above for claim 3, a claim reciting both making and using steps is not indefinite. Therefore, claim 12 is not indefinite. Therefore, the rejection of claim 12 is improper and should be withdrawn.

C. **Claims 20 and 21**

In the office action, the examiner rejects claims 20 and 21, stating that:

> Claim 20 recites intended use for the composition recited in claim 16 from which it depends. Accordingly, claim 20 is indefinite in not further limiting claim 16 from which it depends.
>
> Claim 21 recites intended use for the composition recited in claim 16 from which it depends. Accordingly, claim 21 is indefinite in not further limiting claim 16 from which it depends.

Claims 16, 20, and 21 read as follows.

16. (Previously Presented) A composition, comprising: a mixture of food for an animal and a liposome-encapsulated anti-lipase antibody.

20. (Previously Presented) The composition of claim 16 wherein said food is food for a mammal.

21. (Previously Presented) The composition of claim 16 wherein said food is food for an avian.

In response, the applicant cancels claims 20 and 21.

D. **Claims 34, 35, and 42**

In the office action, the examiner rejects claims 34, 35, and 42, stating that:

> Claim 34 is indefinite in reciting method steps of making a composition which depends from a method of using a composition. Accordingly, it is unclear how the method steps in claim 33 should cooperatively, structurally, and functionally apply to claim 31 from which it depends.
>
> Claim 35 is indefinite in reciting method steps of making a composition which depends from a method of using a composition. Accordingly, it is unclear how the method steps in claim 34 should cooperatively, structurally, and functionally apply to claim 31 from which it depends.
>
> Claim 42 is indefinite in reciting, "A method of using a composition", albeit "formed by a process ... because the claim is drawn to a method of using a composition already formed, whereas "providing a solution", and "adding liposomes . . . to make a solution" encompass a method of forming. Accordingly, it is unclear how these method of forming steps should cooperatively, structurally, and functionally apply to the actual method of use step in the claim.

Claims 34, 35 depend from claim 32. Claims 32, 34, 35, and 42, read as follows.

> 32. (Previously Presented) A method of using a liposome-encapsulated anti-lipase antibody comprising:
>
> 34. (Currently Amended) The method of claim 32 further comprising freeze drying said liposome-encapsulated anti-lipase antibody.
>
> 35. (Currently Amended) The method of claim 32 further comprising mixing said liposome-encapsulated anti-lipase antibody with food for said animal.
>
> 42. (Previously Presented) A method of using a composition formed by a

process comprising:

providing a solution including anti-lipase antibodies; and

adding liposomes to said solution to make a solution containing said liposome encapsulated anti-lipase antibodies; and

comprising feeding said composition to an animal.

In response, the applicant submits that the rejections of claims 34, 35, and 42 are improper for the same reasons specified for claim 3. Specifically, claims reciting both making and using steps are proper under 35 USC 112, second paragraph, those steps are necessarily "cooperatively, structurally, and functionally" related, and 35 USC 112, second paragraph does not require a "cooperatively, structurally, and functionally" relationship there between. Therefore, the rejections of claims 34, 35, and 42 are improper and should be withdrawn.

VI. THE WITHDRAWN REJECTIONS UNDER 35 USC 103 BASED UPON LECLERCQ

The examiner withdrew the rejections based upon Cook et al. (US Patent 5,919,451) in view of Drent et al. (Lipase inhibition: a novel concept in the treatment of obesity, International Journal of Obesity 17: 241-244 (1993)) and in further view of LeClercq et al. (Metabolism of very low density lipoproteins in genetically lean or fat lines of chicken, Reproduction, Nutrition, Development, 30 (6): 701-715 (1990)), and replaced them with rejections of all claims under 35 UCS 103 as obvious based only upon Cook in view of LeClercq. Apparently, the examiner agrees that Drent is not relevant to the claimed inventions.

VII. THE CURRENT OBVIOUSNESS REJECTIONS BASED UPON COOK AND LECLERCQ

The examiner rejects claim 1-5 and 12-42 under 35 USC 103 as obvious based upon Cook and LeClercq.

In response, the rejections are improper for two reasons. First, Cook (USP 5,919,451) is not legal prior art. Second, even if Cook were legal prior art, the combined teachings of Cook and LeClercq do not suggest what is defined by the claims.

A. **The Obviousness Rejections Are Improper Because Cook (USP 5,919,451) is Not Prior Art**

1. The Proof of Actual Reduction To Practice Not Later Than July 7, 1997

A copy of the specification of 08/888,202 filed July 7, 1997 was previously filed as ATTACHMENT 6.

A 37 CFR 1.131 declaration of the inventor Julio Pimentel, attesting to the specification of 08/888,202 being filed July 7, 1997, and that he is the inventor of both that application and this application, was previously filed as ATTACHMENT 8.

The applicant has shown that the claimed inventions were reduced to practice not later than the July 7, 1997 filing date of 08/888,202. As stated in the 131 declaration and in the applicant's prior remarks, Examples 1-6 in our specification show successful production and use of antibodies to anti lipase. Examples 7-10 in our specification show that experiments actually using liposome encapsulated antibodies to anti lipase were effective for their intended purpose. See the 131 declaration of Julio Pimentel. These are actual reductions to practice having a date not later than the filing date of the 08/888,202 application. Accordingly, the 131 declaration and 08/888,202 show a date of invention for what this application claims that antedates the Cook patent's filing date. Therefore, the Cook patent is not prior art.

The examiner disagrees, apparently believing that the 37 CFR 1.131 showing was insufficient, stating that:

> A) Applicant states that he is the inventor of ASN 081888,202 filed on July 7, 1997, which discloses subject matter consonant to the instant application. Applicant states that in ASN 081888,202, Example 7 shows preparation of LE anti-lipase Ab and Example 8-10 show the antibody's use in feeding animals and effectiveness in inhibiting lipase action in animals.
>
> In response, Examiner concurs that LE anti-lipase Abs and its use are disclosed in ASN 08/888,202.
>
> However, it is noted that the instant application does not claim the benefit of priority of ASN 08/888,202. Accordingly, the benefit of priority of the instant application is its effective filing date. [Office action dated 2/9/2007 page 21 lines 6-12.]

In response, the applicant submits that the examiner misunderstood or overlooked the fact that the 131 declaration showed actual reductions to practice. Specifically, the examples in 08/888,202 were actual reductions to practice, as stated in the 131 declaration, shown to be "effective to inhibit lipase in animals." Paragraph 6. And, as stated in the applicant's prior remarks. Thus, the applicant submits that the examiner erred when interpreting the 131 evidence. Moreover, the claim chart in the prior response, and the claim chart in this response, shows the correspondence of the claimed elements to the examples in 08/888,202. Therefore the applicant has shown actual reduction to practice of the claims not later than July 7, 1997.

2. **The 35 USC 102 Prior Art Date of the Cook Patent**

The Cook patent is USP 5,919,451 filed as 09/037,690 3/10/1998. The Cook patent is prior art to all inventions made after 3/10/1998. 35 USC 102(e), which states in pertinent part that:

> A person shall be entitled to a patent unless — (e) the invention was described in... (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent....

The Cook patent issued from an application filed March 10, 1998. March 10, 1998 is not "before the July 7, 1997 proved date of] invention by the applicant for patent." Therefore, the Cook patent is not 102(e) prior art.

The Cook patent claims to be a CIP of application No. 08/684,785, filed Jul. 22, 1996, now U.S. Pat. No. 5,725,873, issued Mar. 10, 1998. However, that does not affect the 102(e) prior art date of the Cook patent. All the CIP claim means as that some portion of the Cook patent's specification was earlier filed in 08/684,785. MPEP 201.08 defines CIP, stating that:

> A continuation-in-part is an application filed during the lifetime of an earlier nonprovisional application, repeating some substantial portion or all of the earlier nonprovisional application and adding matter not disclosed in the said earlier nonprovisional application. (In re Klein, 1930 C.D. 2, 393 O.G. 519 (Comm'r Pat. 1930)).

Moreover, the disclosures of the Cook patent is in fact greater that the disclosure of its CIP parent application, 08/684,785. Thus, there is no logical reason to accord the Cook patent the prior art date for purposes of 35 USC 102 of its parent application. In fact, the law does not accord a prior art

date under 102(e) as of a CIP parent application's filing date to an issued patent. Several cases the holdings of which are binding on the examiner have construed 35 USC 102(e) as to the prior art date applicable to a parent application. None of them conclude the disclosure obtains a prior art date under 102 earlier than the actual date the disclosure was filed in the USPTO.

The examiner's conclusion that the prior art date of the Cook patent is the filing date of its CIP parent is directly contradictory to the holding in In re Klesper, 55 CCPA 1264, 397 F.2d 882, 158 USPQ 256 (CCPA 1968)("As shown above, appellant having conceded that the patent fully meets the appealed claims, the only question at issue is whether the parent Frost application discloses the claimed subject matter.").

Moreover, even the disclosure of the priority application is only legally prior art under 102(e) as of its filing date if and only if a substantive claim in the issued patent has 112 first paragraph support in the priority application. In re Wertheim, 646 F.2d 527, 536-37, 209 USPQ 554, 563, 564 (CCPA 1981).)("Additionally, it is at this point in the analysis that §120 enters the picture, for the phrase in §102(e), "on an application for patent," necessarily invokes §120 rights of priority for prior co-pending applications. If, for example, the PTO wishes to utilize against an applicant a part of that patent disclosure found in an application filed earlier than the date of the application which became the patent, it must demonstrate that the earlier-filed application contains §§120/112 support for the invention claimed in the reference patent.") Even then, Cook patent is not entitled to the filing date of its priority application for purposes of 102(e); only the disclosure of the priority application is entitled to that date. There is no showing by the examiner that the Cook CIP parent provides 112 first paragraph support for a claim in the Cook patent. Thus, there is no basis to conclude from the Cook patent that its CIP parent application's disclosure is prior art.[3]

Therefore, the 35 USC 102 prior art date to which the Cook patent is entitled under 35 USC 102 is its filing date: 3/10/1998. In re Klesper, 55 CCPA 1264, 397 F.2d 882, 158 USPQ 256 (CCPA 1968); In re Wertheim, 646 F.2d 527, 536-37, 209 USPQ 554, 563, 564 (CCPA 1981); and Litton

---

[3]The applicant recognizes that the parent of the Cook patent in fact issued into a patent. However, the examiner did not base a rejection of any claim upon that other patent. For the reasons presented in the prior response, the disclosure of the CIP parent application would not support a rejection of any claim in this application.

Sys., Inc. v. Whirlpool Corp., 728 F.2d 1423, 1438, 221 USPQ 97, 106 (Fed. Cir. 1984). Since the applicant has shown a date of invention, a reduction to practice, of what is claimed, prior to 3/10/1998, the rejections based upon the Cook patent are improper, would necessarily be reversed upon appeal, and should be withdrawn.

The following table shows the support in the specification of 08/888,202 for what is claimed in this application, noting in particular support from examples which constituted actual reduction to practice.

CLAIM IN THIS APPLICATION	SUPPORT IN 08/888,202, citations to page and line numbers in ATTACHMENT 5
1. A method comprising: feeding an animal food and a liposome-encapsulated anti-lipase antibody.	Page 1 lines 14-16. Example 7-10 spanning pages 10-12.
2. The method of claim 1 wherein said anti-lipase antibody is an avian antibody.	Example 1 spanning pages 5 and 6.
3. The method of claim 2 further comprising at least one of storing said liposome-encapsulated anti-lipase antibody in a wet state and freeze drying said liposome-encapsulated anti-lipase antibody.	Example 7 spanning pages 10 and 11.
4. The method of claim 1 wherein said animal is a mammal.	Page 1 lines 5-10 (field of the invention).
5. The method of claim 1 wherein said animal is an avian.	Page 15 lines 4-5 (claim 1).
6-11. (Canceled).	
12. The method of claim 1 further comprising forming said liposome-encapsulated anti-lipase antibody prior to said feeding.	Page 10 lines 15-16.

13. The method of claim 1 wherein said animal food comprises dietary lipid.	-
14. The method of claim 1 wherein said animal food comprises 25 to 1000 mg of said liposome-encapsulated anti-lipase antibody per kilogram of animal food.	-
15. The method of claim 1 wherein said animal food comprises at least 25 mg of said liposome-encapsulated anti-lipase antibody per kilogram of animal food.	Page 11 line 15 (750 mg/KG).
16. A composition, comprising: a mixture of food for an animal and a liposome-encapsulated anti-lipase antibody.	Page 11 line 15 (750 mg/KG).
17. The composition of claim 16 which contains 25-1000 mg of said liposome-encapsulated anti-lipase antibody per kilogram of said food.	Page 11 line 15 (750 mg/KG).
18. The composition of claim 16 wherein said anti-lipase antibody is an avian anti-lipase antibody.	Example 1 pages 5-6.
19. The composition of claim 16 wherein said liposome-encapsulated anti-lipase antibody is in one of a wet state and a freeze dried state.	Example 7 spanning pages 10 and 11.
20. The composition of claim 16 wherein said food is food for a mammal.	Page 1 lines 5-10 (field of the invention).
21. The composition of claim 16 wherein said food is food for an avian.	Page 15 lines 4-5 (claim 1).

22. The composition of claim 16 wherein said food comprises dietary lipid.	-
23. The composition of claim 16 wherein said food comprises at least 25 mg of said liposome-encapsulated anti-lipase antibody per kilogram of animal food.	Page 11 line 15 (750 mg/KG).
24. The composition of claim 23 wherein said anti-lipase antibody is an avian anti-lipase antibody.	Example 1 pages 5-6.
25. A method of making a composition, said composition comprising a mixture of food for an animal and a liposome-encapsulated anti-lipase antibody, said method comprising: forming said liposome-encapsulated anti-lipase antibody; mixing said liposome-encapsulated anti-lipase antibody with said food.	See claims 1 and 17.
26. A composition comprising a liposome-encapsulated anti-lipase antibody.	See claim 1.
27. The composition of claim 26 wherein said anti-lipase antibody is an avian anti-lipase antibody.	See claim 3.
28. The composition of claim 26 wherein said liposome-encapsulated anti-lipase antibody is in a freeze dried state.	See claim 19.

29. A method of making a liposome-encapsulated anti-lipase antibody comprising: forming said anti-lipase antibody; and encapsulating said anti-lipase antibody with liposomes to form said liposome-encapsulated anti-lipase antibody.	See claim 1.
30. The method of claim 29 wherein said anti-lipase antibody is an avian anti-lipase antibody.	See claim 3.
31. The method of claim 29 further comprising freeze drying said liposome-encapsulated anti-lipase antibody.	See claim 19.
32. A method of using a liposome-encapsulated anti-lipase antibody comprising: feeding said liposome-encapsulated anti-lipase antibody to an animal.	See claim 1.
33. The method of claim 32 wherein said anti-lipase antibody is an avian anti-lipase antibody.	See claim 3.
34. The method of claim 32 further comprising freeze drying said liposome-encapsulated anti-lipase antibody.	See claim 19.
35. The method of claim 32 further comprising mixing said liposome-encapsulated anti-lipase antibody with food for said animal.	See claim 1.

36. A method of making a composition comprising: providing a solution including anti-lipase antibodies; and adding liposomes to said solution to make a solution containing said liposomes.	See Example 7 spanning pages 10 and 11.
37. The method of claim 36 further comprising freezing said solution containing said liposomes.	See claim 19.
38. The method of claim 36 further comprising freeze drying said solution containing said liposomes.	See claim 19.
39. A composition formed by a process comprising: providing a solution including anti-lipase antibodies; and adding liposomes to said solution to make solution containing said liposomes.	See Example 7 spanning pages 10 and 11.
40. The composition of claim 39 wherein said process further comprises freezing said solution containing said liposomes.	See claim 19.
41. The composition of claim 39 wherein said process further comprises freeze drying said solution containing said liposomes.	See claim 19.

42. A method of using a composition formed by a process comprising: providing a solution including anti-lipase antibodies; and adding liposomes to said solution to make a solution containing said liposome encapsulated anti-lipase antibodies; and comprising feeding said composition to an animal.	See Example 7 spanning pages 10 and 11.

For the reasons presented above, the subject matter defined by independent claims 1, 16, 25, 26, 29, 32, 36, 39, and 42 is not obvious in view of Cook and LeClercq. While the dependent claims define additional limitations which each may be non-obvious over prior art, no reason exists to explore those issues in view of the foregoing conclusions.

B. **The Obviousness Rejections are Improper Because Cook and LeClercq Do not Suggest What is Claimed**

1. **The Teachings of the Cook USP 5,919,451 Patent**

Cook USP 5,919,451 is directed to a method for improving the growth efficiency or the efficiency of feed conversion of an animal. Title. It discloses (abstract) "feeding the animal feed particles having an inner core of nutrients and an outer layer containing a conjugated fatty acid or an antibody that can protect the animal from contacting diseases...." Cook's Background section describes giving animals antibiotics, immunizing animals, and feeding animals avian antibodies to antigens to prevent intestinal diseases. Cook's Summary of the Invention section states in pertinent part that:

> In a preferred embodiment of the invention, antibodies are provided in solution or suspension in an aqueous or lipid carrier, although the antibodies can be applied directly to the pellet core without a carrier as, for example, a powder. The antibodies can be, but need not be, encapsulated in the lipid.

Cook's Detailed Description section states that:

> The antibodies for use in the present invention are those which can alter physiological processes that adversely affect growth and feed efficiency. They can be

antibodies that are against diseases or specific endogenous regulators of food intake and gastrointestinal motility. The antibodies are preferably derived from the eggs of hens which have been previously immunized to produce those antibodies as described in U.S. Pat. Nos. 4,748,018 or 5,080,895. Especially preferred as the antibody-containing material are spray dried egg yolks and whole eggs. However, other non-egg derived antibody-containing materials may be used.

The only actual antibody disclosed in Cook is antibody to CCK. The only antigen actually discloses in Cook is CCK. See Cook columns 4-6. According to Wikepedia, Cholecystokinin (CCK;) is a peptide hormone of the gastrointestinal system responsible for stimulating the digestion of fat and protein. Cholecystokinin, previously called pancreozymin, is secreted by the duodenum, the first segment of the small intestine, and causes the release of digestive enzymes and bile from the pancreas and gallbladder, respectively. It also acts as a hunger suppressant. See http://en.wikipedia.org/wiki/Cholecystokinin. A copy of http://en.wikipedia.org/wiki/Cholecystokinin was previously submitted as ATTACHMENT 1.

Cook's examples are only for feed including CCK antibodies compared to a control feed. These examples show that feed including the antibody to CCK reduces weight gain (Table 1); and increases feed conversion efficiency (Table 2).

Cook's results are contradictory in that its sole example is an antibody to a protein (CCK) that stimulates digestion of fat and protein. Use of such an antibody would logically decrease digestion of fat and protein leading to decreased feed conversion efficiency. However, Cook's results show increased feed conversion efficiency and weight gain. Cook's results are in accord with its stated goal of feeding "antibodies ... which can alter physiological processes that *adversely* affect growth and feed efficiency..."

Cook does not disclose feeding anti-lipase antibodies. In contrast to Cook, this application discloses feeding liposome-encapsulated anti-lipase antibodies. Cook's stated goal is to inhibit "physiological processes that adversely affect growth and feed efficiency." In contrast to Cook's stated goal, this application discloses that feeding liposome-encapsulated anti-lipase antibodies decrease feed conversion efficiency, and reduce weight gain, and increase weight loss. This goal is exactly the opposite goal, and exactly the opposite effect, obtained by Cook' liposome encapsulated antibodies to

CCK.

2. **THE TEACHINGS OF LECLERCQ**

LeClercq's teaches that intravenously injecting LPL antibody into chickens suppresses LPL activity in the chickens. LeClercq also discloses feeding birds low fat diets. (Animals and Diets section on page 702); preparation of antibodies to LPL (lipoprotien lipase; an enzyme that cleaves a fatty acid from a triglyceride; page 703); intravenous injecting chickens with antibodies to LPL (pages 703-704); and suppression results (remaining pages).

3. **THE COMBINED TEACHINGS OF COOK AND LECLERCQ**

Cook teaches feeding antibody to CCK improves feed conversion efficiency.

LeClercq relates only to the effect of antibodies in the blood, not in the gut. Thus, LeClercq provides no teaching relevant to Cook. Specifically, LeClercq provides no teaching suggesting efficacy of making and feeding anti lipase antibodies.

Accordingly, the teachings of LeClercq are unrelated to the teachings of Cook and provide no suggestion of any kind with respect to modifying what Cook discloses.

Further, neither Cook nor LeClercq suggests inhibiting anti lipase or ingesting a liposome coated anti lipase antibody.

Moreover, neither Cook nor LeClercq provide a teaching suggesting a reasonable expectation of success for any goal of making and feeding animals antibodies to anti lipase. The only disclosed feeding results in Cook are the results for the antibodies produced in response to CCK. The efficacy of such results does not provide a suggestion or a reasonable expectation of success for any process involving anti lipase. As a result, the rejections are for combinations and modifications of the prior art that are clearly based upon hindsight, and therefore improper, would be reversed upon appeal, and therefore should be withdrawn.

In the office action, the examiner states the following reason for combining Cook and LeClercq:

> It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute the anti-lipase antibodies as taught by LeClercq that are specific for lipase antigen produced in the gut, for the antibodies that are liposome encapsulated taught in the method of Cook, that are also specific for antigens present in the gut such as CCK, for feeding to animals in solution or as feed composition, because

anti-lipase antibodies specific for lipase antigen as taught by LeClercq and CCK antibodies specific for CCK antigen as taught by Cook, constitute obvious variations of antibodies specific for antigens known in the art, to be produced and inherently present in the gut, and that Cook specifically taught that they can be liposome-encapsulated for incorporation with food intake. [Office action page 8 last line to page 9 line 11.]

The applicant respectfully disagrees. The foregoing statement does not express any reason to substitute antibodies to Lipase for Cook's CCK. Just because LeClercq shows LPL has an effect in the blood provides no suggestion to one skilled in the art that it would have any effect when ingested. In addition, consider the core reasoning that "anti-lipase antibodies specific for lipase antigen as taught by LeClercq and CCK antibodies specific for CCK antigen as taught by Cook, constitute obvious variations of antibodies specific for antigens known in the art, to be produced and inherently present in the gut". What does that mean? Why is it relevant? " constitute obvious variations " for what use? The applicant submits that the statement is meaningless, and that it is clearly an improper hindsight attempt to piece together a motivation not present in the prior art to arrive at the applicant's claimed invention where no such motivation exists.

LeClercq only teaches that anti-lipase antibodies are effective to inhibit lipase activity in the blood. Surely, the effectiveness of an anti body in the blood does not provide a motivation or reasonable expectation of success to feeding that antibody! No prior art suggested feeding anti-lipase antibodies, and there was no indication what the effect of feeding anti-lipase antibodies would be; no scientific evidence existed. Therefore, neither Cook nor LeClercq provided a suggestion to feed anti-lipase antibodies, and certainly neither Cook nor LeClercq provided an expectation of success that feeding anti-lipase antibodies to animals would provide a useful effect. In contrast to the prior art, claim 1 recites "feeding an animal food and a liposome-encapsulated anti-lipase antibody." Accordingly, the rejections are improper and should be reversed. Accordingly, claim 1 would not have been obvious in view of the applied prior art. The same reasons apply to all of the remaining claims.

4. **SECONDARY INDICIA OF NON OBVIOUSNESS**

In Graham, the court indicated that evidence of anything contradicting a prima facie case of obviousness was probative. Two such types of evidence exist in this case. The first is that the conclusion of the examiner regarding the Cook parent patent, USP 5,725,873, that that patent (which is

admittedly more limited than the disclosure in the Cook 5,919,451 patent) was only enabling for its CCK example. See the file history of USP 5,725,873. Second, evidence exists in US patents showing the uncertainty in effectiveness of anti bodies generated in eggs in response to anti nutritional factors injected into hens. See USP 6,793,921, USP 5,827,517, and USP 5,989,548.

A copy of the file history of USP 5,725,873 is Attachment 2.

A copy of USP 6,793,921 is Attachment 3.

A copy of USP 5,827,517 is Attachment 4.

A copy of USP 5,989,548. is Attachment 5.

a. **The Conclusions Reached by the Examiner of USP 5,725,873 are Contrary to the Obviousness Conclusion Reached by the Examiner in this Application**

In the file history of the CIP parent of the Cook patent, now USP 5,725,873, the examiner thereof concluded that the disclosure therein of feeding a liposome encapsulated antibody to CCK was not enabling for any substance except liposome encapsulated antibody to CCK. As a result, the originally broad claims in the application resulting in were limited during prosecution to define only a feed containing antibodies to CCK. See USP 5,725,873. More specifically, in CIP parent of the Cook patent, the examiner concluded that:

> ...the specification, while being enabling for providing animals with antibody to cholecystokinin (CCK), does not reasonably provide enablement for [broad claims to] passively immunizing an animal against antigens which could reduce the animal's ability to grow or to efficiently convert its feed into desirable body tissue. The specification does not enable any person skilled in the art to which 10 it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. *** *Given the-nature of the invention, which is to enhance the digestive process, it would require undue experimentation on the part of a skilled artisan to determine which other antigens that are active in digestive processes would be suitable as targets for antibodies which are administered orally by the method of the present invention.* [Interpolation supplied.]

What this portion of the file history of the Cook CIP parent indicates is that Cook's teachings

relating to antibodies to CCK do not enable any other types of antibodies. This conclusion is contrary to the conclusion in the office action in this application that the Cook patent, which also only has examples of antibodies to CCK, is a suitable basis to legally suggest, because legal suggestion requires a presumption of enablement, feeding antibodies to some other nutritional related factor than CCK. As a result, even if the Cook 5,919,451 patent was prior art, the obviousness rejections based primarily thereon would be improper.

The undersigned notes that Cook was awarded broader claims in the Cook 5,919,451 patent than in its CIP parent. The disclosure of Cook's 5,919,451 is greater than in the Cook CIP parent. However, the 112 lack of enablement issue was improperly addressed by the applicant in the file history of the Cook 5,919,451, in two ways. A copy of the file history of the Cook 5,919,451 patent was previously submitted as ATTACHMENT 9. As a result, the Cook 5,919,451 patent's claims should not have issued for the same reason the broad claims originally filed by Cook in its CIP parent did not issue in USP 5,725,873. Those reasons are presented below.

First, Cook asserted the fact that his CIP parent application was allowed and issued into USP 5,725,873, was a reason to withdraw enablement rejections in the application that issued into Cook 5,919,451. See the file history of the Cook 5,919,451 paper 7, Amendment A, third and fourth (unnumbered) pages; pages 59 and 60 of the file history. A copy of the file history of the Cook 5,919,451 patent was previously submitted as ATTACHMENT 9. That was improper because the only claim allowed in the application that issued into the Cook USP 5,725,873 was the claim limited to CCK.

Second, Cook cited the existence of WO 96/04933, stating that that PCT publication was "of record, wherein a number of suitable gut peptides known to those skilled in the art are described for use in a related method." However, WO 96/04933 is another one of Cook's early works with CCK. It is entitled "CCK Antibodies Used to Improve Feed Efficiency". All of its studies and results are for CCK. It contains no assertion that its inventors invented anything other than its CCK inventions. What it does state is the hypothesis that, "by generating antibodies to peptides, hormones, and cytokines, etc., that regulate biochemical, metabolic, and Physiological, and/or behavioral processes, *it may be possible* to regulate or alter an animal's system to compensate for a physical abnormality or accentuate a normal function." Page 8 lines 18-23; italics added. That is, it "suggests" that "similar responses could be

achieved ... [for] gastrin... somatostatin, ...bombesin... [and] neuropeptide Y...." Paragraph spanning pages 8 and 9. In other words, the WO 96/04933 provides mere speculation about possible inventions; no more than the Cook CIP parent disclosed. Perhaps motivation to experiment, but not a reasonable expectation of success. Motivation to experiment is insufficient to provide legal obviousness:

> The PTO presents, in essence, an "obvious to experiment" standard for obviousness. However, selective hindsight is no more applicable to the design of experiments than it is to the combination of prior art teachings. There must be a reason or suggestion in the art for selecting the procedure used, other than the knowledge learned from the applicant's disclosure. Interconnect Planning Corporation v. Feil, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985). Of the many scientific publications cited by both Dow and the PTO, none suggests that any process could be used successfully in this three-component system, to produce this product having the desired properties. [In re Dow Chemical Co., 837 F.3d 469, ___, 5 USPQ2d 1529, 1532 (Fed. Cir. 1988).]

Moreover, as described in the next section in this response, most of the specific compounds that were subject to the speculation in WO 96/04933 *failed in fact* to provide the desired effect, as illustrated by subsequent work. This is objective evidence that there was no reasonable expectation of success for antibodies to compounds other than CCK, based upon Cook's disclosures.

A copy of WO 96/04933 was previously submitted as ATTACHMENT 10.

b. **There is Additional Objective Evidence Supporting the Conclusion Efficacy of Feeding AntiBodies to CCK to affect metabolism did not Provide a Reasonable Expectation of Success for any Other Nutrition Related Factor**

Objective evidence indicates that the examiner's conclusions on lack of enablement were soundly based. That evidence is the result of tests presented in USP 6,793,921 and USP 5,827,517 showing no efficacy for antibodies to certain other nutrition related factors. That test data shows that some of the antibody treatments were effective, and some were not effective. USP 5,827,517 reports in its example 9 (spanning columns 9 and 10) on the feeding of *antibodies* to Bombesin, Motilin, and Neuropeptide Y. (Note the title of example 9: "Feeding Anti-Peptides to Broiler Chicks". The example

9 results at column 10 lines 50-55 refer to the peptides, which appears to be short hand for the tested anti peptides.) Of those three, only antibodies to Neuropeptide Y had an effect on weight gain or feed conversion efficiency differing from the control group. Thus, antibodies to all but one of the nutritional factors tested in USP 5,827,517, failed to show any effect. Moreover, that is despite the strong effect the actual nutritional factors had on weight gain or feed conversion efficiency noted in USP 5,827,517's example 12 at columns 13 and 14.

Similarly, USP 5,989,548 shows that feeding antibodies to Bravo provided no substantial effect compared to the control group. See USP 5,989,548 example 11 in columns 11 and 12.

Similarly, USP 6,793,921 also shows the unpredictability in this area of technology. It states that:

> The present invention was made based on the above discovery suggesting that antibodies against whole cells of Hp are not sufficient and antibodies against urease of Hp and/or flagella of Hp are effective for completely inhibiting the colonization of Hp in gastric mucosa to inhibit the growth of Hp in the stomach. It was further found that the combination of each or both of these antibodies and at least one organism selected from lactic acid bacteria, Enterococcuses, yeasts and Bacillus has a synergistic effect.

The point of this disclosure is that "antibodies against whole cells of Hp [H. pylori ; a bacteria in the lining of the stomach] are not sufficient " indicating that an antibody to yet another factor present in digestive systems was ineffective.

Julio Pimentel, inventor of this application, agrees with the interpretation of USP 5,827,517, USP 5,989,548, and USP 6,793,921. Julio Pimentel 37 CFR 1.132 declaration stating that interpretation was previously submitted as ATTACHMENT 7.

Keep in mind that US patents tend to report only successful experiments - those supporting patentable inventions. Hence, the fact that USP 5,827,517, USP 5,989,548, and USP 6,793,921 evidence failed experiments using antibodies suggests that other researchers tried and failed on antibodies to yet digestive and nutritional related substances for which results do not appear in other US patents. In any case, the evidence presented here shows that the art was very uncertain as to what antibodies, if any, to nutritional factors, other than CCK, would show an effect. As a result, the

showing in USP 5,919,451 that feeding antibodies to CCK had an effect, objectively did not provide a reasonable expectation of success for feeding of antibodies to any other nutritional factor, such as antibodies to the claimed anti lipase.

On 12/27/2006, upon reviewing the draft of the prior response, the undersigned noted a facsimile from inventor Pimentel dated 12/12/2006 in which Dr. Pimentel provided abstracts of two additional relevant studies. A copy of the FAX from Dr. Pimentel containing abstracts of two additional studies was previously submitted as ATTACHMENT 11. This FAX was in response to a verbal request from the undersigned to Dr. Pimentel requesting Dr. Pimentel to review the literature and provide to the undersigned any additional publications showing that the results of ingestion of antibodies was uncertain. It does not represent a complete list of studies showing results of studies of ingestion of antibodies. On 12/27/2006, the undersigned was informed by an Anitox telephone receptionist that Dr. Pimentel was on vacation, and therefore the undersigned could not define the scope of Dr. Pimentel's review. However, both abstracts in ATTACHMENT 10 report on experimental use of antibodies apparently generated using Hen eggs, and apparently ingested, and which failed to achieve the intended effects. Moreover, the first Abstract (Effect of egg yolk antibody on experimental Cryptosproidium perfringens colonization in gastrointestinal tract or broiler chickens") indicates additional adverse effects (increased "intestinal lesion scores"). Thus, ATTACHMENT 11 evidences both the lack of certainty of efficacy for ingestion of antibodies generated via hen eggs to a particular antigen, but also the lack of certainty as to detrimental side effects. Thus, ATTACHMENT 11 is additional objective evidence supporting the conclusion that there would be no reasonable expectation of success for the claimed invention at the time the claimed invention conceived or reduced to practice by Dr. Pimentel.

Attachment 12 was previously submitted and it is a copy of a FAX from Dr. Pimentel dated 12/18/2006 providing background information available apparently as of the 2005 year noted on the bottom of some of the pages of this FAX relating to anti nutritional factors. The undersigned includes the information in case the examiner considers it relevant to any issue raised in this amendment merely as a precaution to ensure compliance with rule 56.

VIII. THE PROVISIONAL NON-STATUTORY DOUBLE PATENT REJECTIONS

The office action provisionally rejects claims 1, 2, 16, 18, 19, 26-28, 32, and 33 for non statutory double patenting over claims 1, 8, 14, 18, 31, 47, and 51 of 08/888,202.

The inventor of 08/888,202 was kind enough to provide the claims now pending in that application to the undersigned. A copy of Dr. Pimentel's email identifying the claims pending in 08/888,202 is attachment 15, and pdf image of the claims in the file attached to that email is attachment 16.[4] According to the inventor of 08/888,202, those claims read as follows:

1. (currently amended) A method for inhibiting lipase activity in a mammal, said method comprising the step of: administering to the mammal an avian antibody that decreases activity of lipase relative to a control, wherein said control does not receive said avian antibody.

2-4 (cancelled)

5-6 (withdrawn)

7 (cancelled)

8 (currently amended) The method of claim 1, wherein prior to the step of administering to the mammal said avian antibody, said avian antibody is produced in avian eggs.

9-10 (withdrawn)

11 (cancelled)

12-13 (withdrawn)

14 (previously amended) The method of claim 1, wherein prior to the step of oral administering said avian antibody, said avian antibody is first freeze dried or spray dried.

15-16 (withdrawn)

17 (cancelled)

18 (previously amended) The method of claim 1, wherein said avian antibody is fed in powder form.

19-22 (cancelled)

---

[4] A copy of Dr. Pimentel's email identifying the claims pending in 08/888,202 is attachment 15 A pdf image of the claims in the file attached to Dr. Pimentel's email (attachment 15) is attachment 16.

23-24 (withdrawn)

25-30 (cancelled)

31 (previously amended) The method of claim 1, wherein said avian antibody is fed in liquid form.

32-46 (cancelled)

47 (currently amended) A method of inhibiting absorption of fat in mammals by inhibiting lipase activity, said method comprising the step of :

administering anti-lipase avian antibody that decreases activity of lipase relative to a control.

48-50 (withdrawn)

51 (currently amended) The method of claim 47, wherein said step of orally administering anti-lipase avian antibody comprises orally administering said anti-lipase avian antibody in combination with the mammal's feed or food.

52-54 (cancelled)

Thus, claims 1, 8, 14, 18, 31, 47, and 51 of 08/888,202 define administering in combination with feed or food (claim 51) in powder form (claim 18) or liquid form (claim 31) to the mammal an avian antibody produced in avian eggs (claim 8) and first freeze dried or spray dried (claim 14) that decreases activity of lipase (claims 1 and 47).

In reply, the applicant traverses the provisional rejections (1) for lack of ripeness and (2) due to lack of non statutory double patenting.

First, double patenting rejections over 08/888,202 are not ripe for consideration. The rejection is provisional because 08/888,202 is still pending. On information and belief, 08/888,202 is under final rejection. If 08/888,202 is abandoned, the provisional rejection will be moot. In addition, the examiner has not indicated that any claim in this application is allowable, except for the rejection for double patenting. Therefore, this issue is not ripe for consideration.

Second, there is no non statutory double patenting. Non statutory double patenting is a legal doctrine designed to prevent unjustified extension of the patent monopoly. The Court of Customs and Patent Appeals laid out the policy in In re Schneller, 397 F.2d 350, 158 USPQ 210 (CCPA 1968),

stating that:

> It is at this point that we have to disagree with appellant. True, there is no double patenting in the sense of claiming the same invention because ABCX and ABCY are, in the technical patent law sense, different inventions. The rule against "double patenting," however, is not so circumscribed. The fundamental reason for the rule is to prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about. [In re Schneller, 397 F.2d 350, ___, 158 USPQ 210, 214 (CCPA 1968).]

Unjustified extension of a patent monopoly exists under two circumstances: when a genus is claimed for an earlier patented species, and when the later claimed invention is obvious in view of the subject matter defined by the claim of the earlier issued patent. Eli Lilly & Co. v. Barr Laboratories Inc., 222 F.3d 973, ___, 55 USPQ2d 1609, 1619 (Fed. Cir. 2000); and Georgia-Pacific Corp. v. United States Gypsum Co., 195 F.3d 1322, 1326, 52 USPQ2d 1590, 1593 (Fed. Cir. 1999).

Application of these tests to the claims in this application and the claims in 08/888,202 results in the conclusion that there is no non statutory double patenting.

First, no claim in this application is a genus of a claim in 08/888,202. This is at least because all claims in this application define a method of making, a method of using, or a product containing either liposome-encapsulated anti-lipase antibody, or a solution containing liposomes and anti-lipase antibody, and no claim in 08/888,202 contains any of those limitations.

Second, no claim in this application is obvious in view of the subject matter defined by claims in 08/888,202. Again, no claim in 08/888,202 defines a method of making, a method of using, or a product containing either liposome-encapsulated anti-lipase antibody, or a solution containing liposomes and anti-lipase antibody, and all claims in this application define at least one of those limitations. There is nothing in the prior art suggesting modifying the subject matter claimed in 08/888,202, which is administering to a mammal avian produced antibodies that decrease activity of lipase, to suggest either encapsulating those antibodies with liposomes or placing those antibodies in a solution containing liposomes, as defined by all claims in this application. Therefore, no claim in this application defines subject matter that would have been obvious in view of the subject matter defined by the claims in 08/888,202. Therefore, the double patenting rejections of claims 1, 2, 16, 18, 19, 26-

28, 32, and 33 for non statutory double are improper and should be withdrawn.

IX. EVIDENCE IN THIS APPLICATION

A listing of the attachments submitted in this application follows. Attachments 13-16 are submitted herewith.

A copy of http://en.wikipedia.org/wiki/Cholecystokinin is ATTACHMENT 1.

A copy of the file history of USP 5,725,873 to Cook is ATTACHMENT 2.

A copy of USP 6,793,921 is ATTACHMENT 3.

A copy of USP 5,827,517 is ATTACHMENT 4.

A copy of USP 5,989,548. is ATTACHMENT 5.

A copy of the specification of 08/888,202 filed July 7, 1997 is attached as ATTACHMENT 6.

A 37 CFR 1.132 declaration of Julio Pimentel stating his interpretation if cited patents is ATTACHMENT 7.

A 37 CFR 1.131 declaration of the inventor Julio Pimentel, attesting to the specification of 08/888,202 being filed July 7, 1997, and that he is the inventor of both that application and this application, is ATTACHMENT 8.

A copy of the file history of the Cook 5,919,451 patent is ATTACHMENT 9.

A copy of WO 9604933 is ATTACHMENT 10.

A copy of a fax from inventor Julio Pimentel containing abstracts of two studies is ATTACHMENT 11.

A copy of a FAX from Dr. Pimentel dated 12/18/2006 providing background information available apparently as of the 2005 year noted on the bottom of some of the pages of this FAX relating to anti nutritional factors is ATTACHMENT 12.

A copy of Ex parte Hanna, Appeal No. 2005-2464, application 10/095,715 (November 22, 2005, BPAI) Caroff, Hanlon, and Poteate, APJs is attachment 13.

A copy of the reply brief referred to in Ex parte Hanna, is attachment 14.

A copy of Dr. Pimentel's email identifying the claims pending in 08/888,202 is attachment 15.

A pdf image of the claims in the file attached to Dr. Pimentel's email (attachment 15) is attachment 16.

Truly,

8/3/2007 /RichardNeifeld#35,299/

DATE Richard A. Neifeld

Attorney of Record

Reg. No.: 35,299

RAN/BTM/ran

Date/time code: August 3, 2007 (3:22pm)

Y:\Clients\Anitox Corporation\ANIT0018\ANIT0018U-US\Drafts\Amendment_ANIT0018U-US_8-3-2007.wpd